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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/821,025	03/19/1997	HENDRIK LOUIS BIJL	246152006900	3574

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MORRISON & FOERSTER LLP
3811 VALLEY CENTRE DRIVE
SUITE 500
SAN DIEGO, CA 92130-2332

[REDACTED] EXAMINER

MARX, IRENE

[REDACTED] ART UNIT [REDACTED] PAPER NUMBER

1651

DATE MAILED: 06/10/2003

47

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	08/821,025	BIJL ET AL.	
	Examiner Irene Marx	Art Unit 1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) Responsive to communication(s) filed on 31 March 2003.
- 2a) This action is **FINAL**. 2b) This action is non-final.
- 3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) Claim(s) 68-95 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) Claim(s) _____ is/are allowed.
- 6) Claim(s) 68-95 is/are rejected.
- 7) Claim(s) _____ is/are objected to.
- 8) Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) The specification is objected to by the Examiner.
- 10) The drawing(s) filed on _____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) The proposed drawing correction filed on _____ is: a) approved b) disapproved by the Examiner.
If approved, corrected drawings are required in reply to this Office action.
- 12) The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) All b) Some * c) None of:
 1. Certified copies of the priority documents have been received.
 2. Certified copies of the priority documents have been received in Application No. _____.
 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
a) The translation of the foreign language provisional application has been received.
- 15) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- | | |
|--|--|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s). _____ . |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ . | 6) <input type="checkbox"/> Other: _____ . |

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The application should be reviewed for errors. Error occurs, for example, in the spelling of "fungae" throughout the claims. Error occurs, also in the recitation of "between... to" in claim 68. Generally, the accepted phrase is "between... and" or "from... to". Correction is required.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 3/31/03 has been entered.

Claims 68-95 are being considered on the merits.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Double Patenting

Claims 68-80, 82-86, 94 and 95 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 28-29 of U.S. Patent No. 6,441,208. An obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but an examined application claim not is patentably distinct from the reference claim(s) because the examined claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985).

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Although the conflicting claims are not identical, they are not patentably distinct from each other because the claims are similarly directed to a granule composition comprising microbial biomass which contains at least one polyunsaturated fatty acids, such as *Mortierella*. From Examples 13, 14 and 19 in the patent it is clear that the granules as claimed are extruded and have a size within the required range. From the table it is clear that various microorganisms and products are obtainable from the granules. Thus, it is apparent that the granules are porous at least to some extent. Also, because of the drying temperature of 68° C, which is a suitable pasteurization temperature, one of ordinary skill in the art would have reasonably expected the cells to be dead. That at least some of the cells are non-disrupted would reasonably be expected because of the size of the particles.

Therefore, the inventions are co-extensive.

Claim Rejections - 35 USC § 102/103

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 68-69, 76-80, 82, 84-87, 94-95 are rejected under 35 U.S.C. 102(b) as anticipated by or, in the alternative, under 35 U.S.C. 103(a) as obvious over Barclay.

The claims are directed to a granule composition comprising extruded microorganisms which are dead and non-disrupted and which are porous and have a diameter between 0.1 mm and 12 mm.

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Barclay discloses a granule composition comprising extruded microorganisms, which are dead and non-disrupted. See, e.g., col. 12, lines 32-60. This granular composition is presumed to be inherently porous at least to some extent and to have a diameter between 0.1 mm and 12 mm. The referenced composition appears to be identical to the presently claimed composition and is considered to anticipate the claimed composition, since it is prepared by the same process and is useful for the same purpose of providing omega-3 highly unsaturated fatty acids, for example, from unruptured cells by extraction (See, e.g., col. 13, lines 13-20). The process of extrusion inherently results in biomass that is porous, at least to some extent, since the material is disclosed as forming an "extruded matrix" (See, e.g., col. 12, line 47). Consequently, the claimed composition appears to be anticipated by the reference.

In the alternative, even if the claimed composition is not identical to the referenced composition with regard to some unidentified characteristics, the differences between that which is disclosed and that which is claimed are considered to be so slight that the referenced composition is likely to possess the same characteristics of the claimed composition particularly in view of the similar process of making by granules by extrusion of biomass and the property of allowing the extraction of fatty acids therefrom, for example, which they have been shown to share. Note the teachings of the reference regarding the various drying and extrusion processes (See, e.g., col. 12, lines 32-60). Thus the claimed composition would have been obvious to those skilled in the art within the meaning of USC 103.

Accordingly, the claimed invention as a whole was at least *prima facie* obvious, if not anticipated by the reference, especially in the absence of evidence to the contrary.

Claims 68-95 are rejected under 35 U.S.C. 103(a) as being unpatentable over Barclay taken with Carduck *et al.*, Akimoto *et al.*, Casey *et al.* and Remington *et al.*.

Barclay discloses a granule composition comprising extruded microorganisms, which are dead and non-disrupted. See, e.g., col. 12, lines 32-60. The referenced composition is prepared by the same process and is useful for the same purpose of providing omega-3 highly unsaturated fatty acids, for example, from unruptured cells by extraction (See, e.g., col. 13, lines 13-20). The process of extrusion results in a biomass that is granular and porous, as adequately demonstrated by Carduck (See, e.g., col. 4, last paragraph).

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The references differ from the claimed invention in the nature of the microorganisms involved and in the presence of specific compounds in these microorganisms and may differ in the size of the particles or granules as well as the percentage of pores. However, Akimoto *et al.* adequately demonstrate that *Mortierella*, a yeast, is known to contain polyunsaturated fatty acids such as arachidonic acid which can be extracted with a solvent (See, e.g., Table 1). In addition, the reference discloses that *Aspergillus* is also a suitable source of compounds that can be extracted with a solvent. In addition, Casey *et al.* adequately demonstrate that *Pichia*, also a yeast, is known to contain tetraacetyl sphingosine (TAPS) which can be extracted with a solvent (See, e.g., page 3, lines 32 et seq.).

Therefore, it would have been obvious to one having ordinary skill in the art at the time the claimed invention was made to modify the product of Barclay by selecting another dried extruded microbial granular product containing dead microorganisms, such as further yeasts or fungi, including *Pichia* containing TAPS, as suggested by Casey *et al.* or *Mortierella* or *Aspergillus* as suggested by Akimoto *et al.* for the expected benefits of providing a valuable dried granular product that is porous and which is stable and easy to handle from which desired chemical compounds are extractable through the pores.

With respect to the specific content of dry matter and the specific sizes and percentage of porosity, it is apparent that these limitations are met by the composition of Barclay, but even if they are not, the selection of particle size is within the skill of the ordinary artisan in this art, as adequately demonstrated by Remington *et al.*. See, e.g., pages 1623-1627. In particular, the reference states that particle-size distribution can be controlled by varying the speed of rotation and drying temperature as well as by comminuting the granulation to the desired granule size after drying (page 1624, col. 2, last paragraph).

Thus, the claimed invention as a whole was clearly prima facie obvious, especially in the absence of evidence to the contrary.

Applicant's arguments with respect to the claims of record have been considered but are moot in view of the new ground(s) of rejection.

No claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Irene Marx whose telephone number is (703) 308-2922. The examiner can normally be reached on Monday through Friday from 6:30 AM to 3:00 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Wityshyn, can be reached on (703) 308-4743. The appropriate fax phone number for the organization where this application or proceeding is assigned is before final (703) 872-9306 and after final, (703) 872-9307.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to Customer Service whose telephone number is (703) 308-0198 or the receptionist whose telephone number is (703) 308-1235.

Irene Marx

Irene Marx
Primary Examiner
Art Unit 1651

BMK/JAH
BRUCE KISLIUK, DIRECTOR
TECHNOLOGY CENTER 1600